

Via E-Filing

August 29, 2011

Re: U.S. ex rel. Strom v. Scios, Inc. and Johnson & Johnson, No. C 05-3004 CRB (JSC)

Dear Judge Corley,

Plaintiff, the United States of America, and Defendants, Scios, Inc. and Johnson & Johnson, submit this joint letter requesting that the Court resolve a dispute involving a third-party witness, Dr. Raymond Lipicky. Counsel have met and conferred by letter, telephone, and in person, and are unable to resolve the dispute. We respectfully request a decision prior to Dr. Lipicky's September 23, 2011 deposition (which is one week prior to the fact discovery cut-off).

The Issue. Defendant Scios, Inc. (Scios) claims attorney-client privilege as to discussions its former employees had with Dr. Lipicky, an outside consultant. The United States disputes the claim of privilege and seeks to depose Dr. Lipicky on the discussions, and to re-depose former Scios employees who were instructed not to answer questions on the discussions. In addition, to the extent Defendants have withheld documents reflecting communications between Scios and Dr. Lipicky, the United States seeks to compel their production.

The United States' Position. The United States alleges that Defendants caused the submission of false or fraudulent claims to federal health care programs in violation of the False Claims Act, 31 U.S.C. §§ 3729-33, by marketing and promoting the drug Natrecor for serial, scheduled outpatient infusions — a use not approved by the Food and Drug Administration (FDA) and not covered by the federal health care programs.

Various Scios employees had a telephone call with Dr. Lipicky in March 2002 to discuss the boundaries of Natrecor's FDA-approved label, specifically as it relates to treatment setting, including outpatient heart failure clinics. (Dickinson Depo., Ex. 7; Horton Depo., Ex. 8.) At that time, Dr. Lipicky was a former FDA employee. He was not employed by Scios, but was being used as an independent outside consultant by Scios. (E.g., Dickinson Depo. at 123:24-25.)

During the investigation phase of this case, the United States interviewed Scios' former Marketing Director, George Mahaffey, in the presence of his counsel. Mr. Mahaffey told the government about the March 2002 conversation between Scios and Dr. Lipicky, and described its content. According to Mr. Mahaffey, the Scios participants on the call were himself, President Richard Brewer, Regulatory Affairs employee Michael Crockett, and Vice President of Regulatory Affairs Jane Moffitt. According to deposition testimony, Senior Vice President of Clinical Research and Medical Affairs Darlene Horton and Regulatory Affairs employee Klara Dickinson were also on the call, among others. (Horton Depo. at 241:1-12.)

At his interview, Mr. Mahaffey refrained from disclosing other discussions that Scios had regarding Natrecor's label because he stated that those discussions involved attorneys. However, Mr. Mahaffey did not state that the March 2002 call with Dr. Lipicky involved attorneys; nor did he indicate that the call was confidential. Mr. Mahaffey's counsel, who claims a joint privilege with Defendants and their counsel, did not object to the questioning. (See Mahaffey Depo. at 18:4-5.) Based on the information received from Mr. Mahaffey, the United States knows the content of Scios' March 2002 call with Dr. Lipicky, and views it as important evidence in

establishing Defendants' violation of the False Claims Act.

At his deposition, Mr. Mahaffey was instructed by defense counsel not to answer questions regarding Scios' conversation with Dr. Lipicky. (Mahaffey Depo. at 79:14 to 80:24, 133:3-13, 246:5-23.) Other witnesses were similarly instructed not to answer. (Moffitt Depo. at 215:23 to 216:19; Horton Depo. at 225:3-17, 231:12-25, 232:9 to 234:2, 238:7-19; Garrett Depo.- transcript not yet available.)¹ In contrast, Mr. Brewer and Ms. Dickinson were permitted to answer similar questions – in some instances, the exact questions that others were instructed not to answer. However, Mr. Brewer and Ms. Dickinson testified that they did not recall the answers. (Brewer Depo. at 60:13-19; Dickinson Depo. at 136:10-19, 139:9 to 140:8.) By permitting Mr. Brewer and Ms. Dickinson to answer questions about the content of the call with Dr. Lipicky without asserting privilege, Defendants waived their claim of privilege. See Brandon v. D.R. Horton, Inc., 2008 WL 2096883 at *3 (S.D. Cal. May 16, 2008) (“failure to assert the attorney-client privilege, especially during deposition, is an absolute waiver of the privilege”).

In addition, another witness, Russell Cox, testified about what appears to have been a different telephone call that Scios had with Dr. Lipicky in October 2003, which involved an attorney from an outside law firm. Mr. Cox was instructed not to answer what was discussed on that call. (Cox Depo. at 276:6 to 278:3, 282:3 to 283:2.)

Defendants' claim of privilege with respect to the March 2002 call is based on the fact that Jane Moffitt, Scios' Vice President of Regulatory Affairs, was on the call. Ms. Moffitt had a law degree; however, she has testified that the degree was not necessary for her job. (Moffitt Depo. at 250:21 to 251:4.) In any event, even assuming arguendo that Ms. Moffitt was acting as an attorney for Scios, the discussions with Dr. Lipicky were not privileged because Dr. Lipicky was a third-party consultant, not an employee of Scios. This also applies to any other discussions that Scios employees may have had with Dr. Lipicky when attorneys were present.²

For communications with a company's attorneys and an outside consultant to be covered by the company's attorney-client privilege, the Ninth Circuit requires the consultant to be the functional equivalent of an employee. United States v. Graf, 610 F.3d 1148, 1158-59 (9th Cir. 2010) (individual was functional employee, not independent outside consultant, where he communicated with third parties on behalf of company, managed company employees, and was the company's primary agent in its communications with corporate counsel). Dr. Lipicky was not the functional equivalent of a Scios employee. He did not manage Scios employees; he did not have authority to act on behalf of Scios; he was not the primary contact person at Scios for

¹ Jane Moffitt and Darlene Horton also discussed the content of the March 2002 call in their pre-litigation interviews with the government. During her interview, Ms. Moffitt did not claim she was acting as an attorney during the phone call. Nor did Defendants object to Ms. Moffitt's interview on the ground that she was acting as an attorney for Scios.

² Dr. Horton testified that Scios in-house counsel Matt Hooper may have been on the March 2002 call, but she did not remember. (Horton Depo. at 241:14-15.)

anything; he did not have authority to enter agreements on Scios' behalf; and there is no evidence that he acted as a spokesperson for Scios, communicated to third parties on Scios' behalf, or had the authority to do so. (Dickinson Depo. at 133:20-24, 134:18-22, 135:7 to 136:6; Cox Depo. at 278:18-20, 279:12-24; Horton Depo. at 242:21 to 243:22.)

All of Defendants' cited cases in which disclosure to a third party did not waive the privilege find either that the third party was the functional equivalent of an employee (as in Graf), or that the third party's participation in an attorney-client communication was necessary to facilitate the communication (i.e., the third party was analogous to an interpreter for the attorney). See NXIVM Corp. v. O'Hara, 241 F.R.D. 109, 138-41 (N.D.N.Y. 2007). There is no evidence that Dr. Lipicky acted in the nature of an interpreter between Ms. Moffitt and the other Scios employees on the call. Instead, Scios was seeking advice from an outside consultant regarding the boundaries of Natrecor's label. There is testimony that no Scios attorney even spoke during the March 2002 call with Dr. Lipicky; moreover, defense counsel instructed Dr. Horton not to answer a question seeking to determine whether Dr. Lipicky's role in the call was to help counsel communicate with Scios employees. (Horton Depo. at 241:16 to 242:2.)

Accordingly, Defendants waived any privilege claim by permitting Mr. Brewer and Ms. Dickinson to answer deposition questions about Scios' call with Dr. Lipicky, and in any event, Defendants do not have a valid claim of privilege regarding Scios' discussions with Dr. Lipicky.

The United States' Request for Relief. First, the United States respectfully seeks a ruling from the Court prior to Dr. Lipicky's September 23 deposition that his discussions with Scios were not privileged. Second, the United States seeks leave to re-depose the witnesses who were instructed not to answer questions regarding their discussions with Dr. Lipicky: George Mahaffey, Jane Moffitt, Darlene Horton, Russell Cox, and Scott Garrett. The United States will endeavor to work out a procedure with Defendants to obtain this information without holding depositions of all five witnesses. Third, the United States asks that Defendants be ordered to produce any documents regarding Scios' discussions with Dr. Lipicky which have been withheld.

Defendants' Position. In March 2002, Scios attorney and Vice President of Regulatory Affairs, Jane Moffitt, undertook a legal analysis of "the boundaries of Natrecor's FDA-approved label, specifically as it relates to treatment setting" See United States' Position, *supra*, at 1.³ As part of that process, Scios retained and consulted with Dr. Ray Lipicky, a former FDA official. See Moffitt Tr. 215:23-217:3, 219:16-221:18. Under the terms of his engagement agreement, Dr. Lipicky reported to Ms. Moffitt and was required to keep all information confidential. See LIPIC001-0020 & LIPIC001-0021. Through this motion, the government

³ Ms. Moffitt was clearly acting in her role as a lawyer, and the government does not seriously claim otherwise. As the government concedes, the issue being addressed was the legal boundaries of Natrecor®'s label. That is quintessential legal advice protected by the attorney-client privilege. See *Upjohn v. U.S.*, 449 U.S. 383, 392 (1981) (holding that corporate attorney's advice regarding "vast and complicated array of regulatory legislation" was protected).

seeks to discover the details of the conversations among Scios' lawyers, other Scios employees, and Dr. Lipicky. Although the government argues that the conversations between Scios and Dr. Lipicky are not privileged, it remarkably does not cite a *single case* in which a court ordered disclosure of communications between company lawyers and a third-party consultant.

For at least two independent reasons, the government should not be able to discover these privileged conversations. *First*, the attorney-client privilege attaches when a company's lawyer discusses legal issues with an outside consultant who "possesse[s] the relevant information the attorney need[s] to render sound legal advice," *Memry Corp. v. Ky. Oil Tech.*, 2007 WL 39373, at *2 (N.D. Cal. Jan. 4, 2007), and is "the sort of person with whom a lawyer would wish to confer confidentiality," *U.S. v. Graf*, 610 F.3d 1148, 1158 (9th Cir. 2010). Indeed, "when applying the attorney-client privilege to a corporation or partnership, it is inappropriate to distinguish between those on the client's payroll and those who are instead, and for whatever reason, employed as independent contractors." *In re Bieter Co.*, 16 F.3d 929, 937 (8th Cir. 1994); *see also Graf*, 610 F.3d at 1159 ("We find the reasoning in *Bieter* persuasive and adopt its principles in the Ninth Circuit."). A company must be allowed to communicate "confidentially with nonemployees who, due to their relationship to the client, possess the very sort of information that the privilege envisions flowing most freely." *In re Bieter*, 16 F.3d at 938.⁴

Although courts sometimes refer to protected third-party consultants as "functional employees," the fact that Dr. Lipicky did not also maintain an office at Scios or direct Scios employees is of no moment. *See, e.g., Memry Corp.*, 2007 WL 39373, at *3 (privilege maintained even though consultant did not have offices at company or supervise employees). Similarly, nothing in *Graf* or any other case cited by the government requires a person to have a managerial role or the authority to execute agreements or speak on behalf of the company, and, indeed, many actual employees do not possess these capacities.⁵

Here, Scios lawyers retained Dr. Lipicky, requesting that he provide information so that the lawyers could properly interpret the label. Dr. Lipicky was bound by his consulting

⁴ In addition to *Memry Corp.* and *Graf*, numerous courts in the Ninth Circuit have found that the attorney-client privilege covers communications with certain third parties. *See Davis v. City of Seattle*, 2007 WL 4166154, at *4 (W.D. Wash. Nov. 20, 2007); *ASU Students for Life v. Crow*, 2007 WL 2725252, at *3 (D. Ariz. Sept. 17, 2007); *Residential Constructors, LLC v. Ace Prop. & Cas. Ins. Co.*, 2006 WL 3149362, at *12-16 (D. Nev. Nov. 1, 2006); *McCaugherty v. Siffermann*, 132 F.R.D. 234, 238-39 (N.D. Cal. 1990).

⁵ Protecting communications with third-parties is particularly important when an attorney "resort[s] to consultation with others in order to render full and complete legal services" and when the purpose of the "third party's participation is to improve the communication between attorney and client." *NXIVM Corp. v. O'Hara*, 241 F.R.D. 109, 140-41 (N.D.N.Y. 2007). That is exactly what happened here. The purpose of Dr. Lipicky's involvement was to assist Scios lawyers to provide full and complete legal advice to the company related to the Natrecor® label and to assist in understanding the "complicated array of regulatory legislation confronting the modern corporation." *Upjohn*, 449 U.S. at 392.

agreement to maintain the confidentiality of all Scios-related information he received. Dr. Lipicky's role was to aid lawyers who were providing legal advice to the company. It would be unfair and contrary to the attorney-client privilege and the authorities cited above to allow the government access to these confidential and privileged conversations.

Second, the conversations the government seeks to discover were in the context of meetings of Scios' attorneys and corporate management (at which Dr. Lipicky was also present). The mere presence of a third party does not waive the attorney client privilege in such circumstances. Waiver only occurs when "a party discloses privileged information to a third party who is not bound by the privilege, or otherwise shows disregard for the privilege by making the information public." *Bittaker v. Woodford*, 331 F.3d 715, 719 (9th Cir. 2003); *see also NXIVM Corp.*, 241 F.R.D. at 138 ("[A] disclosure to a third party does not waive the privilege unless such disclosure is inconsistent with the 'maintenance of secrecy' and if the disclosure 'substantially increases the possibility of an opposing party obtaining the information.'") (citations omitted). Here, of course, Scios has not made the privileged information public, and Dr. Lipicky was bound to keep the information confidential.

Finally, there is no merit to the government's contention that Scios "waived" the privilege by failing to object to certain questions during the depositions of Mr. Brewer and Ms. Dickinson. Neither deponent revealed *any* privileged information. As the government admits, neither Mr. Brewer nor Ms. Dickinson recalled *anything* substantive concerning the conversations at issue, making it impossible to reveal any privileged information.⁶ "Merely disclosing the fact that there were communications or that certain subjects were discussed with attorneys does not constitute waiver. Rather, the content of the privileged communication with the attorneys must be shared for there to be waiver." *Sleep Sci. Partners Inc. v. Lieberman*, 2010 WL 4316687, at *1 (N.D. Cal. 2010); *see also Quicksilver, Inc. v. Kymsta Corp.*, 247 F.R.D. 579, 584 (C.D. Cal. 2007) (finding no waiver of privilege because deponent "did not reveal the substance of any attorney-client communication in his deposition answer"). As a result, the privilege has not been waived.⁷

For these reasons, Dr. Lipicky's communications with Scios' counsel are protected by the attorney-client privilege and there is no basis to find that this privilege has been waived. Dr. Lipicky should not be required to testify to the discussions at issue, nor should the Government be permitted to reopen the depositions of those deponents who were instructed not to reveal this privileged information.

⁶ In fact, the specific call at issue was not discussed during Mr. Brewer's deposition because Mr. Brewer did not recall speaking to Dr. Lipicky after he left the FDA. (Brewer Tr. 59:24-60:12.) Additionally, Scios' counsel repeatedly lodged privilege objections when Mr. Brewer was asked whether Scios received advice concerning the Natrecor® label. (Brewer Tr. 61:8-64:8.) Similarly, the first time Dr. Lipicky was raised during Ms. Dickinson's deposition, Scios' counsel instructed the witness not to reveal communications involving Dr. Lipicky and Ms. Moffitt or other lawyers on the basis of privilege. (Dickenson Tr. 120:24-121:7.)

⁷ To the extent the government suggests otherwise, nothing revealed by Mr. Mahaffey, Ms. Moffitt, or Ms. Horton during interviews could waive the privilege because the privilege is not theirs to waive. *See U.S. v. Chen*, 99 F.3d 1495, 1502 (9th Cir. 1996).

Respectfully submitted,

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